REMARKS

Claims 1-10 and 13-60 were pending in the Application. Claims 61 to 72 have been added and do not constitute new matter. Claims 1-10 and 13-23 are rejected by the Examiner. Claims 3, 4, and 8 have been canceled without prejudice and the subject matter of these claims has been added to claim 1. Claims 24 to 60 are also canceled without prejudice and without conceding to the Examiner's characterizations. Claims 11 and 12 were canceled in a previous response. Claims 1, 5, 6, 7, 9, 10 and 17 are amended without prejudice and without conceding to the Examiner's characterizations. Reconsideration of the present Application is respectfully requested.

PTO Interview Summary

Applicant hereby submits this Interview Summary regarding the interview with Examiner Wang, and Applicant's attorneys Maryellen Feehery and Edward Behm on February 24, 2004.

Summary of Discussion

Applicant discussed a Declaration by Dr. Gans, which is being filed concurrently herewith (Exhibit 1), claims 1-10 and 13-23 and the cited references (Poulsen U.S. Patent No. 3,934,013 and the PDR entry for Lidex).

The distinction between classes of potency of corticosteroid preparations and the effect of delivery vehicles on potency and corresponding vasoscores were explained with reference to the specification and Dr. Gans' Declaration.

Proposed Amendments to Claims by Examiner

Examiner Wang proposed that the claims be amended to include "penetrations enhancers selected from the group consisting of diisopropyl adipate, dimethyl isosorbide, propylene glycol, 1,2,6-hexanetriol, and benzyl alcohol." Applicant noted that the penetration enhancers were described on page 8 of the specification.

Additionally, the Examiner proposed one set of claims be limited to the corticosteroid, fluocinonide.

Another separate claim set was proposed to include vasoscore limitations. Applicant noted that the pending claims are composition claims and cannot be limited by functional language as set

forth below.

Applicant gratefully acknowledges the Examiner's suggested amendments to the claims and has incorporated those amendments into the pending claims, with the exception of functional limitations, which are discussed below.

Claim Rejections Pursuant to 35 U.S.C. 103

Claims 1-7 and 10-19 stand rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Poulsen. Additionally, Claims 1-23 stand rejected pursuant to 35 U.S.C. §103(a) as being unpatentable Poulsen "in view of PDR entries of Lidex-Synalar."

The Examiner notes that Applicant's prior response directs attention to Table 2 and avers unexpected results residing in different weight ratios of penetration enhancers to the sum of penetration enhancers and solvents and emulsifiers. However the Examiner was not convinced, and did not understand why Applicant called the vasoconstrictor scores "unexpectedly high." Applicant traverses these rejections for at least the reasons stated in the previous response, interview and below.

The Examiner fails to make out a prima facie case of obviousness with respect to Claim 1 as amended. First, a prior art reference or combination of such is required to teach or suggest all claim limitations in order to render a claim obvious. The Examiner notes that "Poulsen. . . does not teach the employment of a second penetration enhancer, neither does it teach the particular excipients herein as recited in claims 21-23." To the extent that Poulsen teaches or suggests increased efficacy, he does so only by increasing the amount of active ingredients (see column 17, lines 60-63, for example) whereas Applicant's claimed ratio does not alter the amount of active ingredients. Unlike Poulsen, the present invention increases potency by altering the inactive ingredients, not the active ingredients. Therefore Poulsen actually teaches away from the present invention.

Further, the PDR reference does not teach the claimed ratio of 0.90. Note that the claimed ratios of the present invention provide an improved potency and an unexpectedly high vasoconstrictor score (as discussed below). Therefore neither Poulsen nor PDR teach all of the claim limitations and there is no teaching or suggesting to combine the references.

The claims must particularly point out the invention, in this case a composition of matter. The pending claims accomplish this. Claims are not the appropriate place to point out advantages of the claimed composition of matter, as this would not further define the composition of matter. Advantageous properties may be mentioned elsewhere, but not in the claims. *See, In re Soni*, 34 USPQ2d 1684 (Fed. Cir. 1995). This is true even of the unexpected advantages that an applicant may rely upon to rebut a *prima facie* case of obviousness. *Id; In re Chupp*, 2 U.S.P.Q.2d 1437 (Fed. Cir. 1987); and *In re Albrecht*, 185 U.S.P.Q.2d 585 (CCPA 1975). In each case, the claims described only the composition. In each case, the applicant relied upon unexpected advantages to rebut a *prima facie* case of obviousness. In each case, the advantages were not mentioned in the claims. In each case, the courts found the claims to be patentable. In this application, as in the above cited cases, the Applicant has relied upon unexpected advantages to demonstrate the nonobviousness of the claims. The Examiner may not refuse to consider this evidence, simply because those advantages are not recited in the claims. Therefore, the showing of the advantages of the claimed invention in the Applicant's specification is sufficient and is commensurate in scope with the present claims.

Dr. Gans, an expert in the dermatologic drug delivery system field and an inventor on this application, has set forth a declaration regarding the unexpected advantages of the present invention, which is attached hereto as Exhibit 1 ("Gans Declaration"). Vasoconstriction scores (or "vaso scores") are measured when topical corticosteroids are applied to the skin (Gans Declaration ¶ 2). "The degree of skin blanching... (i.e. vaso scores) serves as a measure of the inherent potency of the drug." (Gans Declaration ¶ 2)

"The vasoconstrictor assay is the most widely used technique to assess the potency of topical corticosteroid preparations. It correlates well with the clinical efficacy of corticosteroid formulations." (Gans Declaration ¶ 3) Vasoscores are even recognized by the FDA as showing bioequivalence. (Gans Declaration ¶ 3).

The difference in vasoscores (on Table 2) of 85 and above or 71 and below is significant. In Example 1, fluocinonide preparations were tested and according to the prior art, fluocinonide preparations (including commercially available topical fluocinonide composition Lidex) were only Class II (see Table 1 in the specification and Gans Declaration ¶ 8). However, as seen in Table 2, the present invention was unexpectedly able to produce vasoscores for Class I preparations. "The relative potency of topically applied corticosteroids are ranked by class, based on vasoconstrictor

testing, with Class I being the most potent and Class VI being the least potent." (Gans Declaration ¶ 5 and Exhibit C). "The anti-inflammatory activity of topical corticosteroid compositions is based upon differences in vasoconstrictor test scores...For example, Class I topical corticosteroid compositions often exhibit a vasoconstrictor score of 80 or above, while Class II topical corticosteroid compositions often exhibit a vasoconstrictor score of less than 80."

The differences in Class I and II corticosteroid preparations are manifested in clinical and physiological differences, and the U.S. Food and Drug Administration places different restrictions on their use. (Gans Declaration ¶ 7 and Exhibit B).

"Thus, the differences in vasoconstrictor scores of 71 [for the prior art] and 85 [for the present invention] for fluocinonide represents real, clinical and physiological differences by placing fluocinonide in specified vehicles producing these scores into separate classes...The effect of altering of the ratio of [two or more] penetration enhancers to (penetration enhancers and solvents and emulsifiers) which provides for the rise in vasoconstrictor scores from 71 to 85, with the associated rise from Class II to Class I, is an entirely unexpected result." (Gans Declaration ¶ 9)

Thus, Applicant respectfully submits that this rejection has been overcome.

CONCLUSION

Applicant respectfully submits that the application is in condition for allowance. Applicant does not believe any additional fee is required for this Amendment and Request for Reconsideration, however, in the event any additional fee is required or any overpayment credit

is due, the Commissioner is hereby authorized to charge Deposit Account No. 18-0586.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/037,360 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703 872-9306 on the date shown below.

Maryellen Feehery

March 9, 2004
Date of Facsimile Transmission

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